

REMARKS/ARGUMENTS

Status of the Claims

Claims 42-69 and 73-78 are pending in the present application. Claim 70 has been canceled without prejudice to or disclaimer of the subject matter contained therein to further prosecution. Applicants expressly reserve the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in this canceled claim. Claims 42, 48, 55, 58, and 60 have been amended.. Support for the amendments to the claims resides throughout the specification and in the original claims. No new matter is added by way of claim amendment.

Specifically, claim 42 has been amended to recite “wherein said targeting molecule comprises a polypeptide that: (a) forms a closed covalent loop; and (b) contains at least three peptide domains having beta-sheet character, each of the domains being separated by domains lacking beta-sheet character.” Support for this amendment may be found throughout the specification and in the original claims, for example, in original claim 1. Claims 48, 53, 55, 58, and 60 have been amended as suggested by the Examiner. No new matter is added by way of these claim amendment.

New claims 73-78 are directed to a composition comprising a targeting molecule linked to at least one biological agent, wherein said targeting molecule comprises a polypeptide that: (a) forms a closed covalent loop; and (b) contains at least three peptide domains having beta-sheet character, each of the domains being separated by domains lacking beta-sheet character, wherein said polypeptide comprises at least domain 2 of a J chain, and wherein the targeting molecule does not contain at least one of the domains selected from $C_H1\alpha$, $C_H2\alpha$, $C_H3\alpha$ and C_L . Support for these claims may be found in the original claims, for example, in original claim 1, and the specification, for example, on page 12, lines 21-22 and on page 9, lines 18-21. No new matter is added by way of presentation of these new claims; therefore entry of these new claims is respectfully requested.

Reexamination and reconsideration of the claims is respectfully requested. The Examiner's remarks in the Office Action are addressed below in the order set forth therein.

The Non-statutory Double-Patenting Rejection

Claims 42-70 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, and 7 of U.S. Patent No. 6,440,419. Upon notification of allowable subject matter in the present application, Applicants will either timely file a terminal disclaimer compliant with 37 C.F.R. §1.130(b) or will demonstrate that the claims of the present application are patentably distinct from claims 1, 2, 6, 7 of U.S. Patent No. 6,440,419.

Claims 42-70 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending U.S. Application Nos. 08/782,481 and 10/062,467. Upon notification of allowable subject matter in both the present application and one or both of the co-pending applications, Applicants will either timely file a terminal disclaimer compliant with 37 C.F.R. §1.130(b) or demonstrate that the presently claimed subject matter is patentably distinct from the claims of the copending applications; claims 1, 2, 6, 7 of U.S. Patent No. 6,440,419; and the claims of copending Application No. 10/062,467.

The Rejection of the Claims under 35 U.S.C. §112, First Paragraph, Should Be Withdrawn

Claims 42-70 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed as applied to the amended claims for the reasons provided below. It is further submitted that the rejection should not be applied to new claims 73-78.

Claim 42 has been amended to recite that the targeting molecules comprises a polypeptide that: (a) forms a closed covalent loop; and (b) contains at least three peptide domains having beta-sheet character, each of the domains being separated by domains lacking beta-sheet character. New claims 73-78 contain these same limitations. These structural features have been shown by the Applicants to be necessary for a targeting molecule to provide specific targeting to

an epithelial cell and internalization of a biological agent linked thereto (see the Examples section). Accordingly, the new and amended claim recites specific structural features that characterize the claimed genus of targeting molecules, and the requirement for a written description of the invention under 35 U.S.C. § 112, first paragraph, is met.

Claims 42-70 have been rejected under 35 U.S.C. §112, first paragraph, as lacking an enabling disclosure. This rejection is respectfully traversed as applied to the amended claims. It is further submitted that the rejection should not be applied to new claims 73-78.

The Examiner states that the specification, while being enabling for a targeting molecule comprising a J chain and the CH2 and CH3 domains of IgA or IgM, does not reasonably provide enablement for a targeting molecule comprising a portion of a J chain and the CH2 and CH3 domains of IgA or IgM. In addition, the Examiner states that there are no functional or structural limitations to the J chain portion. Claim 42 has been amended as described above to recite that the targeting molecule comprise a polypeptide that: (a) forms a closed covalent loop; and (b) contains at least three peptide domains having beta-sheet character, each of the domains being separated by domains lacking beta-sheet character. New claims 73-78 recite these same limitations. Applicants have shown that these structural features are necessary for binding of the targeting molecule to a basolateral surface of an epithelial cell. Accordingly, one of skill in the art could make and use the targeting molecules recited in claims 42-69 and 73-78 without undue experimentation, and the claims satisfy the requirement for an enabling disclosure under 35 U.S.C. § 112, first paragraph.

In view of the above amendments and arguments, all grounds for rejection under 35 U.S.C. § 112, first paragraph, have been obviated or overcome. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

The Rejection of the Claims under 35 U.S.C. §112, Second Paragraph, Should Be Withdrawn

Claims 48, 53, and 55 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for reciting the phrase “comprises amino acid sequence selected from.” Claims 48, 53, and 55 have been amended as suggested by the Examiner. Therefore, the rejection of claims 48, 53, and 55 as being indefinite should be withdrawn.

Claims 58 and 60 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for reciting “comprises an amino acid sequence from.” Claims 58 and 60 have been amended as suggested by the Examiner. Therefore, the rejection of claims 58 and 60 as being indefinite should be withdrawn.

The Rejection of the Claims under 35 U.S.C. §103(a) Should Be Withdrawn

Claim 70 is rejected under 35 U.S.C. §103(a) as being unpatentable over Max and Korsmeyer (1985) *J. Exp. Med.* 161:832-849 and Janknecht *et al.* (1992) *Gene* 121:321-324. To further prosecution, claim 70 has been canceled, rendering the rejection of this claim moot.

The Objection to Claim 70 Should be Withdrawn

Claim 70 has been objected to under 37 CFR §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. To further prosecution, claim 70 has been canceled, rendering the objection moot, rendering the rejection of this claim moot.

The Objection to the Specification Should be Withdrawn

The Examiner states that the application is not fully in compliance with the sequence rules because SEQ ID NOS: 114-140 are listed in the claims but are not included in the sequence listing. Applicants note that a sequence listing containing sequences 1-140 was submitted to the USPTO on January 17, 2001, and was entered into this case. A review of the file history on PAIR indicates that subsequent to the January 17, 2001 submission, a sequence listing that was intended for U.S. Application Serial No. 09/005,167 was erroneously entered in the present

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application. Because there were errors in the sequence listing for 09/005,167, a Notice of Failure to comply with the requirements for applications containing sequences listings was generated in response, and it appears that Applicants' previous representative responded with a copy of the original sequence listing, which did not contain SEQ ID NOS: 114-140. Applicants note that the sequence listing filed January 17, 2001 complies with the rules of 37 CFR §1.821-1.825, and requests that the Examiner rely on this sequence listing in examining the present application.

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CONCLUSION

Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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Customer No. 00826 ALSTON & BIRD LLP Bank of America Plaza 101 South Tryon Street, Suite 4000 Charlotte, NC 28280-4000 Tel Raleigh Office (919) 862-2200 Fax Raleigh Office (919) 862-2260	<u>CERTIFICATE OF EXPRESS MAILING</u> "Express Mail" Mailing Label Number EV184328285US Date of Deposit: December 23, 2004 I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to MAIL STOP RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 <i>Nora C. Martinez</i> Nora C. Martinez
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